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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,336

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

02/05/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,336	<b>Applicant(s)</b> ONO ET AL.	
	<b>Examiner</b> LEZAH W. ROBERTS	<b>Art Unit</b> 1612	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Applicants' arguments in the Request for Continued Examination, filed October 30, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Oath/Declaration***

Applicant has filed a petition and Corrected Literal English Translation of the International Application as filed to thereby ensure compliance with 35 USC 371 and 37 CFR 1.495. During review of the Application, the petition was GRANTED. During review it was noted that "inspection of the declaration filed on 06 January 2006 reveals that it does not appear to have been made on a form supplied by the USPTO, or under Rule 4.17(iv), and that the statement required under 37 CFR 1.69(b) does not appear to have been made. Applicants are required to either provide such statement or else a new oath or declaration".

Applicant is reminded that once allowable subject matter is indicated, a patent cannot be granted until the above is submitted.

### ***Drawings***

The drawings are objected to because the difference between the tooth before the test and after the test cannot be determined because the drawings appear to be too dark. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## ***Claims***

### **Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the limitation "comprising polyphenols **including** rosmarinic acid".

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the

broad recitation “polyphenols”, and the claim also recites “including rosmarinic acid” which is the narrower statement of the range/limitation.

### **Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

1) Claims 1, 4 and 5 were rejected under 35 U.S.C. 103(a) as being unpatentable over in Melman (US 2002/0156130) in view of Oriza (JP 2000-239136). The rejection is maintained.

#### **Applicant's Arguments**

Applicants again submit that for the reasons of record a prima facie case of obviousness has not been established by any of the rejections of record; and that, even if for the sake of argument a prima facie case of obviousness has been established in any of the rejections, unexpected results associated with Applicants' claimed subject matter are further evidence of patentability of Applicants' claimed subject matter. The Supplemental Declaration shows that in Example 3 wherein *Perilla frutescens* var. *crispa flutescen purpurea* polyphenol was solely used, 50% weight of the dental calculus was dissolved after 105 minutes, and in Example 18 wherein glycolic acid was solely as the active ingredient, 44% weight of the dental calculus was dissolved after 9 minutes. In contrast, Applicants note that when polyphenol and glycolic acid were utilized in combination, there is obtained a more rapid dissolving of the dental calculus, i.e., 50% weight of the dental calculus was dissolved after 6 minutes. Applicant

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asserts that the claims as presently amended places the claims commensurate in scope with the Declaration asserting unexpected results, and therefore the claims should be indicated to be allowable over the prior art of record.

Further, the obviousness rejection based upon Melman in view of Oriza is without appropriate basis and does not establish a prima facie case of obviousness. For the sake of brevity, and in view of the indication at the interview that the application appeared to be in condition for allowance upon presentation of the amended claim 1, Applicants are not repeating each of the arguments as previously submitted, but incorporate the arguments, including the arguments submitted April 30, 2009, as if set forth in full herein.

#### Examiner's Response

In regards to the unexpected results, the claims are still not commensurate in scope with the instant claims. See the indefinite rejection above. Applicant has asserted that the results have a synergistic effect because better results were seen when glycolic acid and an aqueous extract of *Perilla frutescen var. crispa flutescen purpurea* comprising polyphenol, specifically rosmarinic acid, were combined in comparison with the results obtained by each of them separately. Although this appears to be the case, the results do not encompass the claims as recited presently. The claims read on any polyphenol contained in the plant including rosmarinic acid. Further the claims as presently amended, do not recite that rosmarinic acid has to be in an effective amount and it cannot be determined if the results obtained would be the same using different

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polyphenols obtained from an aqueous extract of *Perilla frutescen var. crispa flutescen purpurea*. The results only support the specific extract obtained by Meiji Seika Kaisha, Ltd., which only identifies a rosmarinic content of 3.3% or more.

In regards to the arguments filed April 30, 2009, see Examiner's response mailed August 7, 2009.

2) Claims 3, 6 and 7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Melman (US 2002/0156130) in view of Oriza (JP 2000-239136) as applied to claims 1 and 4 and 5, in further view of Zhu (WO 01/17494) and Tagashira et al. (JP409295944). The rejection is maintained.

#### Applicant's Arguments

See Applicant's Arguments above in regard to Melman in view of Oriza. Applicant does not appear to argue Zhu explicitly but does refer to the arguments filed April 30, 2009.

#### Examiner's Response

See Examiner's Response above. Also see Examiner's response mailed August 7, 2009 in regard to the arguments pertaining to the instant rejection.

Claims 1 and 3-7 are rejected.

No claims are allowed.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612